Expanding Healthcare Failure Mode and Effect Analysis: a composite proactive risk analysis approach

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ABSTRACT

Healthcare Failure Mode and Effect Analysis (HFMEA) is a systematic risk assessment method derived from high risk industries to prospectively examine complex healthcare processes. Like most methods, HFMEA has strengths and weaknesses. In this paper we provide a review of HFMEA's limitations and we introduce an expanded version of traditional HFMEA, with the addition of two safety management techniques: Systematic Human Error Reduction and Prediction Analysis (SHERPA) and Systems-Theoretic Accident Model and Processes – Systems-Theoretic Process Analysis (STAMP-STPA). The combination of the three methodologies addresses significant HFMEA limitations. To test the viability of the proposed hybrid technique, we applied it to assess the potential failures in the process of administration of medication in the home setting. Our findings suggest that it is both a viable and effective tool to supplement the analysis of failures and their causes. We also found that the hybrid technique was effective in identifying corrective actions to address human errors and detecting failures of the constraints necessary to maintain safety.

Keywords: Combined prospective risk analysis, HFMEA, SHERPA, STAMP-STPA.

INTRODUCTION

In the field of safety-critical engineering, a number of risk analysis techniques have been developed and applied. A standard practice in high-risk industries are prospective hazard analysis techniques, like Failure Modes and Effects Analysis (FMEA), Hazard and Operability (HAZOP), Systematic Human Error Reduction and Prediction Approach (SHERPA), Human Error Analysis and Barrier Analysis, just to name a few (Potts et al., 2014). These techniques have been designed with the aim to anticipate and prevent harm in error-prone processes, rather than relying on corrective actions after the incidents have occurred (Potts et al., 2014).

Over the past two decades, similar safety approaches have been adopted in healthcare, in order to analyse high risk processes (Habraken, 2009). One of the most popular methods is Healthcare Failure Mode and Effect Analysis (HFMEA). HFMEA is a five-step multidisciplinary procedure developed by the United States Department of Veterans Affairs' National Center for Patient Safety in 2002. Recent studies have recognised the importance of applying HFMEA to identify potential failures, causes and consequences. It has been largely applied to the processes of administration and ordering of drugs (Wetterneck, 2004; Esmail et al., 2004; Vélez-Díaz-Pallarés et al., 2013), sterilization and use of surgical instruments (Linkin et al., 2005), as well as prevention of errors in radiotherapy (Van Tilburg et al., 2006) and chemotherapy (Cheng et al., 2012).

Despite these numerous applications, experts have debated possible amendments to the HFMEA approach in order to address its limitations (Habraken et al., 2009; Franklin, Shebl, & Barber, 2012). Specifically, it has been suggested that HFMEA could be improved by combining the traditional approach with different risk analysis techniques (Stanton et al., 2004, 2009, 2005, 2013, 2014; Ambrahamsen, 2016).

The aim of this paper is to present an overview of HFMEA's criticisms and introduce an extended, hybrid version of HFMEA obtained with the addition of two supplementary risk assessment tools that can address specific HFMEA limitations – namely Systematic Human Error Reduction and Prediction Approach (SHERPA) and Systems-Theoretic Accident Model and Processes – Systems-Theoretic Process Analysis (STAMP-STPA). The hybrid approach completes the healthcare focused approach (HFMEA) with human factor-focused (HTA and SHERPA) and system-focused (STAMP) approaches. SHERPA steps have analogies with HFMEA steps. For example, both methodologies require to depict the process with diagram with the aim to identify the failures. SHERPA focuses on human error and in this sense, the combination of HFMEA failure identification with SHERPA human error identification leads to the advantages of a socio-technical risk assessment approach. SHERPA consequence analysis is useful to review the severity ratings because it encourages the team members to examine in details the rates in correspondence to the consequences of each failure. STAMP-STPA formalises the HFMEA cause analysis with a system

approach that helps identify the controls and constraints necessary to prevent undesirable interactions between system components.

We further present prospective data to test the viability of the new technique in the context of medication administration in homecare settings. The following paragraph provides an overview of the HFMEA method and its critique.

Healthcare Failure Mode and Effect Analysis (HFMEA) and its limitations

HFMEA is a multidisciplinary method that combines the concepts, the components and the definitions of industrial FMEA, Hazard Analysis Critical Control Point and Root Cause Analysis
HFMEA is a proactive risk analysis method that involves a multidisciplinary team to map out a high-risk healthcare process and identify the potential failures that can occur within the process activities (DeRosier et al. 2002). It comprises five main steps (DeRoiser et al., 2002).. The *first step* consists in the choice of the topic, which usually is a highly vulnerable or/and high risk process of care. The *second step* is establishing a multidisciplinary team. The *third step* is creation of a graphical representation of the process and identification of potential failure modes. This is generally done by means of a box and arrow diagram. For major and complex processes, it is suggested to focus on a single highly vulnerable activity (known as the 'scope' of the analysis). The process diagram aims to guide the team in identification of potential failures for each activity. The *fourth step* is the hazard analysis. During this step, the failures identified in the third step are scored with severity and probability ratings (each using four point scales accompanied by written descriptions) that are multiplied to calculate a hazard score.
Severity is related to the seriousness of the effects of failures; probability of occurrence is the likelihood that failures will occur. The hazard score is intended to guide the team's efforts by highlighting the failures with the highest score (called critical failures) that need attention. The critical failures that warrant further action are then selected using a decision tree, answering questions about the criticality, detectability and presence of control measures. For the critical failures, the potential causes and the potential effects are listed and further examined. Finally, in the *fifth step*, the team formulates recommendations to prevent or mitigate the critical failures with suggested outcome measures to evaluate the effect of the implemented solutions. A worksheet is used to record the failures, their causes, the team's assessment, the proposed actions, and the outcome measures.
HFMEA has been evaluated and critiqued by several authors. Table 1 summarises some of the most common HFMEA limitations and proposed solutions at each step of the process.

Criticisms of HFMEA	Proposed solutions
Graphical description of the process	
• The graphical representation of the process is subjective (Shebl, Franklin, & Barber, 2009). • The box-and-arrow diagram provides only minimal information (Chadwick & Fallon, 2013). • The box-and-arrow diagram does not include a description of the control measures (Chadwick & Fallon, 2013).	Improve the process representation using other diagram types, e.g. task analysis and IDEF∅ - Integrated Definition for Function Modelling (Chadwick & Fallon, 2013; Franklin, Shebl, & Barber, 2012).
Hazard Analysis	
Identification of failures	
• The definition of the potential failures is too subjective (Vélez-Díaz-Pallarés et al., 2013). • Before identification of potential failures, there is a poor consultation of existing evidence (Habraken et al., 2009; Shebl, Franklin, & Barber, 2009; Ashley et al., 2010a-b ; Nagpal et al., 2010) • During the identification of potential failures, human errors are overlooked (Habraken et al., 2009; Franklin et al., 2012; Chadwick & Fallon, 2013).	• Prepare an initial list of failures according to existing evidence to use before the identification of potential failures (Habraken et al., 2009). • Define scenarios and formulate basic assumptions to map the main activities of the process and identify failures (Habraken et al., 2009 ; Chadwick & Fallon, 2013). • Include human error taxonomy to identify human errors (Chadwick & Fallon, 2013)
Scoring of failures	
• The rating procedure could be affected by personal interpretations of probability and severity scales (Wetterneck et al., 2004)(Habraken et al., 2009; Chadwick & Fallon, 2013; Vlayen, 2011). • An inappropriate rating procedure, such as brainstorming, can influence and bias the individual ratings (Ashley et al., 2010a-b). • The HFMEA procedure does not require the identification of the activities at which the error could be recovered(recovery points) (Chadwick & Fallon, 2013). • The decision tree results can be difficult to understand and use (Habraken et al., 2009; Chadwick & Fallon, 2013).	• Adapt the rating scales to the process analysed (Wetterneck et al., 2004; Habraken et al., 2009;Chadwick & Fallon, 2013; Vlayen, 2011). • Rate the failures with a scoring procedure able to determine the individual point of view, i.e. substitute the focus group with an individual confirmatory formal analysis step of prioritizing the failures (Nagpal et al., 2010). • Extend the hazard analysis with the identification of recovery activities (Chadwick & Fallon, 2013). • Change the decision tree to make it more understandable (Chadwick & Fallon, 2013; Habraken et al., 2009).
Cause analysis	
• The HFMEA procedure does not provide guidelines to identify and analyse causes. • The HFMEA procedure does not include guidelines to translate the causes into countermeasures. (Chadwick & Fallon, 2013; Habraken et al., 2009)	Perform a cause analysis with a system approach that takes into account the complexity of processes. (Chadwick & Fallon, 2013;Habraken et al., 2009)
Identification prevention measures and controls	
The HFMEA procedure does not support continuous improvement. (Chadwick & Fallon, 2013)	Improve the prevention measures and controls already in use in the process. (Chadwick & Fallon, 2013)

Table 1 – HFMEA steps with criticisms and proposed solutions

METHODS

HFMEA combined with SHERPA and STAMP-STPA

We chose to combine HFMEA with two proactive risk analysis methodologies: SHERPA and STAMP-STPA. SHERPA supports the study of human-based processes (Lyons et al., 2004) and STAMP-STPA improves the causal analysis with a new classification of causes in terms of unsafe, inadequate or absent controls (hence it adds the perspective of cause as control problems).

Systematic Human Error Reduction and Prediction Analysis (SHERPA)

SHERPA is a human error identification and analysis technique developed by Embrey (1986) to predict human errors in a structured manner in the nuclear industry. It uses Hierarchical Task Analysis (HTA: Stanton, 2006) together with a taxonomy of human errors to identify errors associated with the sequence of activities that compose the process. SHERPA has undergone extensive validation trials (Stanton and Stevenage, 1998; Stanton and Young, 1999a-b; Stanton et al, 2009). It comprises several steps: (Stanton et al., 2005; 2013):

1. The process is broken down into a hierarchy of tasks (i.e., activities executed to achieve the goals) and plans (i.e., the sequence in which the activities are executed). Each task is classified into actions (e.g., pressing a button, pulling a switch, opening a door), retrieval (e.g., getting information from a screen, manual, expert), checking (e.g., conducting a procedural check), selection (e.g., choosing one alternative over another) and information communication (e.g., talking to another party).

2. The activities are evaluated for potential errors using the human error taxonomy. The types of error that may occur fall into one of the aforementioned five categories: action, checking, retrieval, communication and selection. Each error is judged according to its consequences and probability of occurrence. Consequences deemed to be critical (i.e., it causes unacceptable losses, it results in system/process failure or in an adverse event) are noted and assessed for whether the error could be corrected at some point during the process. This is useful to determine the points of weakness (i.e., if the activity fails, the entire process would fail) and identify whether or not there are effective control measures.

3. The final stage is a proposal of error mitigation and reduction strategies. Typically, these strategies can be categorized as equipment, training, procedures or organizational, which can be evaluated by their feasibility and effectiveness.

Research comparing SHERPA with other human error identification methodologies suggests that it performs better than other similar methods in a wide range of scenarios (Kirwan,1992; Stanton et al., 2009). SHERPA has been applied in a wide range of domains, from purchases at vending machines (Baber and Stanton, 1996; Stanton and Stevenage, 1998), through the prediction of pilots' errors (Harris et al., 2005; Stanton et al, 2009) to the assessment of military command and control systems (Salmon et al, 2012). In healthcare, SHERPA has been applied to analyse the nature and the incidence of errors during laparoscopic surgery (Joice et al.,1998) and to detect errors in the process of drug administration in hospital (Lane, Stanton, & Harrison, 2006).

Systems Theoretic Accident Model and Processes & System Theoretic Process Analysis (STAMP-STPA)

STAMP is a modelling approach proposed by Leveson to capture the dynamics of a complex socio-technical system (Leveson, 2004). It is based on the theory that systems are interrelated components linked by feedback loops and the accidents result from inadequate control or inadequate enforcement of safety-related constraints of the system (Leveson, 2004). STPA is the associated hazard identification technique, that is used to predict the causes of an accident in terms of the lack or controls and constraints (Stanton et al., 2013; Qureshi, 2008). The analysis can be conducted in several steps (Leveson, 2013):

1. Create a complete list of control actions starting from a translation of high-level system hazards into safety constraints/requirements.

2. Represent the safety requirements thorough an architectural description, that is a hierarchical control structure of a general socio-technical system (also called functional control structure). This is composed by a basic structure that includes details about the control actions and the feedback relationships - contextualised in control loops, actuators, sensors, controllers, and controlled process (figure 1-A). The actuators are the variables managed by the controller that supposedly guarantees that the safety constraints are respected, the sensors are the elements of the process that give information about its safety state and the controllers (human or automated) are the elements that have a deep knowledge of the process and can control it. The control loop has to be simplified and has to reflect the system of interest (Leveson, 2004; Antoine, 2013). For this reason, it is possible to focus on a single area, such as the operating process of a general socio-technical system (Leveson, 2004).

3. Identification of unsafe control actions and their causes (i.e., events that would lead to the failure of the safety constraints). The identification is done by means of guidewords (e.g., 'inadequate control algorithm', 'control input', 'wrong or missing') provided by Leveson (2004) into a general taxonomy of causal factors. The general taxonomy is articulated into three main categories of unsafe control measures (figure 1-B). It should be adapted to the analysed process (Kazaras et al., 2014).

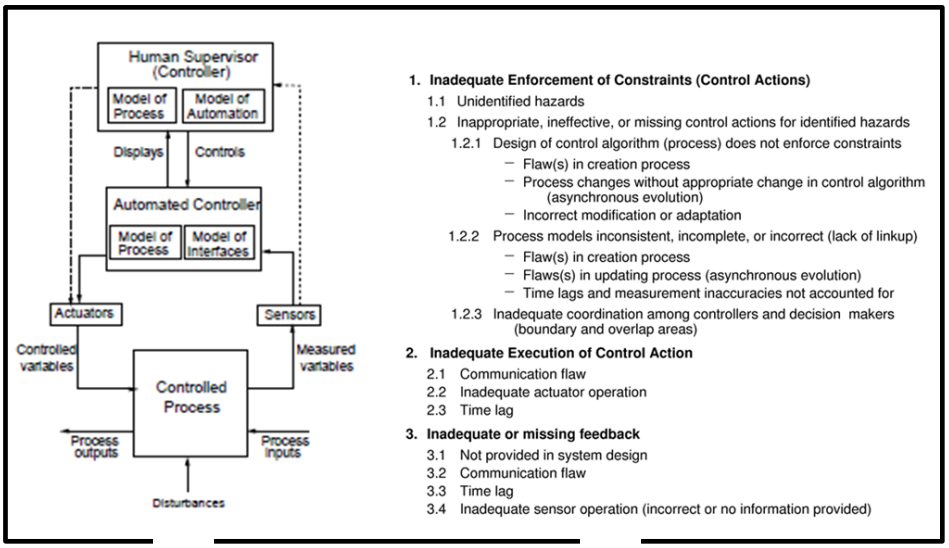
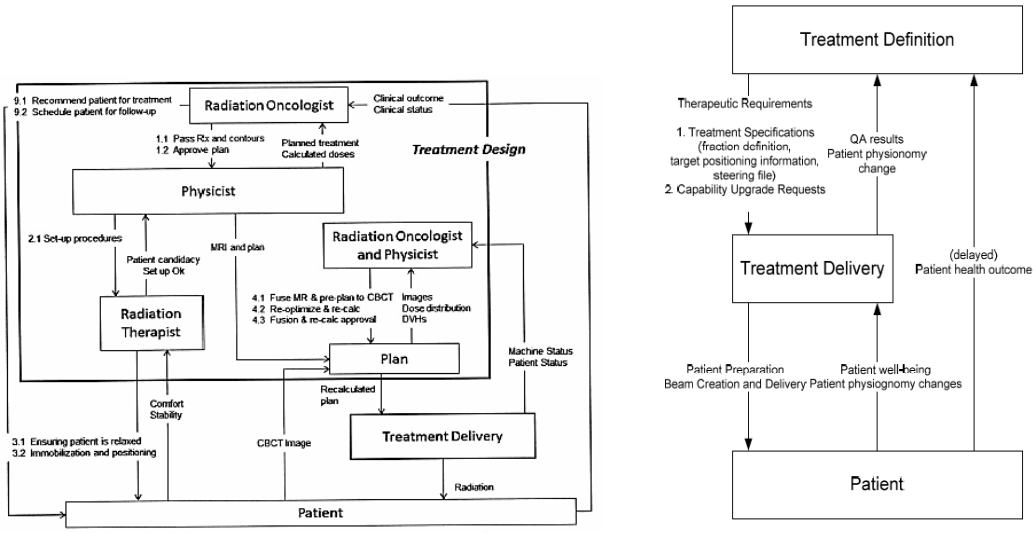


Figure 1 – (A): STAMP-STPA - A typical control loop of an operating process
(B): STAMP-STPA – General taxonomy of causal factors (Leveson, 2004)

STAMP-STPA has been applied in a number of domains, including the investigation of a complex aircraft collision avoidance system, the contamination of a Canadian water supply system and in the construction of road tunnels (Qureshi, 2008; Kazaras et al., 2014). It has been recently applied in the healthcare sector to identify and document the hazards in a radiation oncology process and in a proton therapy system (Samost, 2015; Antoine, 2013). The technique was also tailored to the domain of Medical Application Platforms (Procter et al., 2014). Figure 2 provides an example of control loops of two different healthcare processes.



C **D**

Figure 2 – (C): Control functional loop of radiation oncology process (Samost, 2015). (D): Control functional loop of proton therapy system (Antoine, 2013)

Hybrid HFMEA: the combined approach

Table 2 presents the order of the methods used within our proposed hybrid HFMEA – based on the standard steps of HFMEA, SHERPA and STAMP-STPA arranged in conceptual and chronological sequence.

Hybrid HFMEA				
Steps	**# Sub-Steps**	**HFMEA**	**SHERPA**	**STAMP-STPA**
Graphical description of the process	**1**	Box-and-arrow diagram		
	2		Hierarchical Task Analysis Diagram & Task Classification	Representation of the Control Loop
Hazard Analysis	**3**	Failures identification		
	4		Human error classification	
	5	Failure scoring		
	6		Consequence Analysis	
	7	Check the coherence of severity scores		

	8	Hazard score calculation		
	9		Recovery Analysis and identification of the single point of weakness	
	10	Selection of the critical failures		
	11			List of the existing control measures
Cause Analysis	**12**	Cause identification		
	13			Cause classification
Identification of measures and controls	**14**	Definition of solutions and outcome measures	Remedy Analysis	
	15			Upgrade of the control loop with suggested solutions

Table 2 – Conceptual and chronological sequence of the combined approach

RESULTS

An example: analysis of medication administration in the home setting

In order to verify its feasibility of the hybrid HFMEA, the approach was applied to a healthcare-derived clinical application: medication administration (MA) by informal carers (friends, relatives - (Donelan et al., 2002)) at home (Parand et al., in press). Recent studies have demonstrated that this process is high-risk prone and the home drug-related adverse events are very common (Masotti et al., 2010).

Analysis set up

Before starting the analysis, two researchers (AP & GF) assembled a multidisciplinary team of 14 members with different backgrounds and experiences: researchers with expertise in human factors and ergonomics, pharmacists, elderly care consultants, community nurses, psychologists, patient

representatives, family member informal carers and an outsider; three members had prior expertise in HFMEA.

Successively, as suggested by (Habraken et al., 2009), the team was split up into four small groups of ten people, with an appropriate mix of representatives (e.g., 3 pharmacists, 2 psychologists, 2 patients, 1 elderly care consultant physician, 1 community nurse and 1 family member carer. In addition to a team leader, there were three facilitators with prior expertise in HFMEA. The team included lay members who were not familiar with the specific study topic).

From a review of the literature on safety in MA at home, the researchers (AP & GF) prepared a graphical representation of the process (i.e., box-and-arrow diagram), validated by one informal carer, one nurse and two pharmacists. Since the carers can administer different medications, two scenarios were defined: one for low risk medications (i.e., tablets) and another for high risk (i.e., insulin injections).

Next, the HFMEA severity rating scale was customised with the evidence-based severity scale proposed by Westbrook et al. (2010). Finally, the HFMEA and SHERPA ratings were combined (Table 3). In order to support the collection of the information, a new worksheet was designed (see Appendix A) with the aim to record, for each failure, the SHERPA classification of human error, the consequences, the process recovery points and the hazard scores. The analysis was articulated into four meetings of two hours each (8 hours in total), a duration that is the minimum comparable with other studies (Ashley et al., 2010 b).

	SHERPA ratings		
HFMEA ratings	**High (H)**	**Medium (M)**	**Low (L)**
Severity (S)	Major Catastrophic	Moderate	Minor
Probability (P)	Frequent	Occasional Uncommon	Remote

Table 3 – SHERPA ratings and HFMEA ratings

Graphical description of the process and SHERPA Task Classification

The box-and-arrow diagram of MA process was broken down into SHERPA's hierarchical task analysis (HTA) diagram. The HTA of medication administration process revealed seven main sub-processes and 23 activities/tasks, diversified between tablets and injections (Figure 3).

The graphical representation was then integrated with the STAMP-STPA's control loop (Figure 4). In order to build the control loop, it was necessary to define and identify the controllers, sensors and actuators of the MA process in the domiciliary setting. The controllers were defined as the supervisors of the principle process' steps, such as the informal carers, whose activities are consecutively controlled by the community physicians and/or pharmacists; the sensors were the means used by the controllers to monitor the process and receive information (e.g., regular checks) and the actuators were the means used by the controllers to impose the constraints and avoid dangerous situations (e.g., supporting documents, utensils used for the safe administration of medications and training). All these elements were identified according to official guidelines and policies on MA in domiciliary settings currently in place in Europe and UK.

In accordance with SHERPA's step of Task Classification, each task of the HTA diagram was classified into action, checking, retrieval, information communication or selection with very good agreement (kappa=0.875) by two team members (AP & GF) and the majority of activities were considered to be 'action', followed by 'checks' and 'retrieval' tasks (Figure 3).

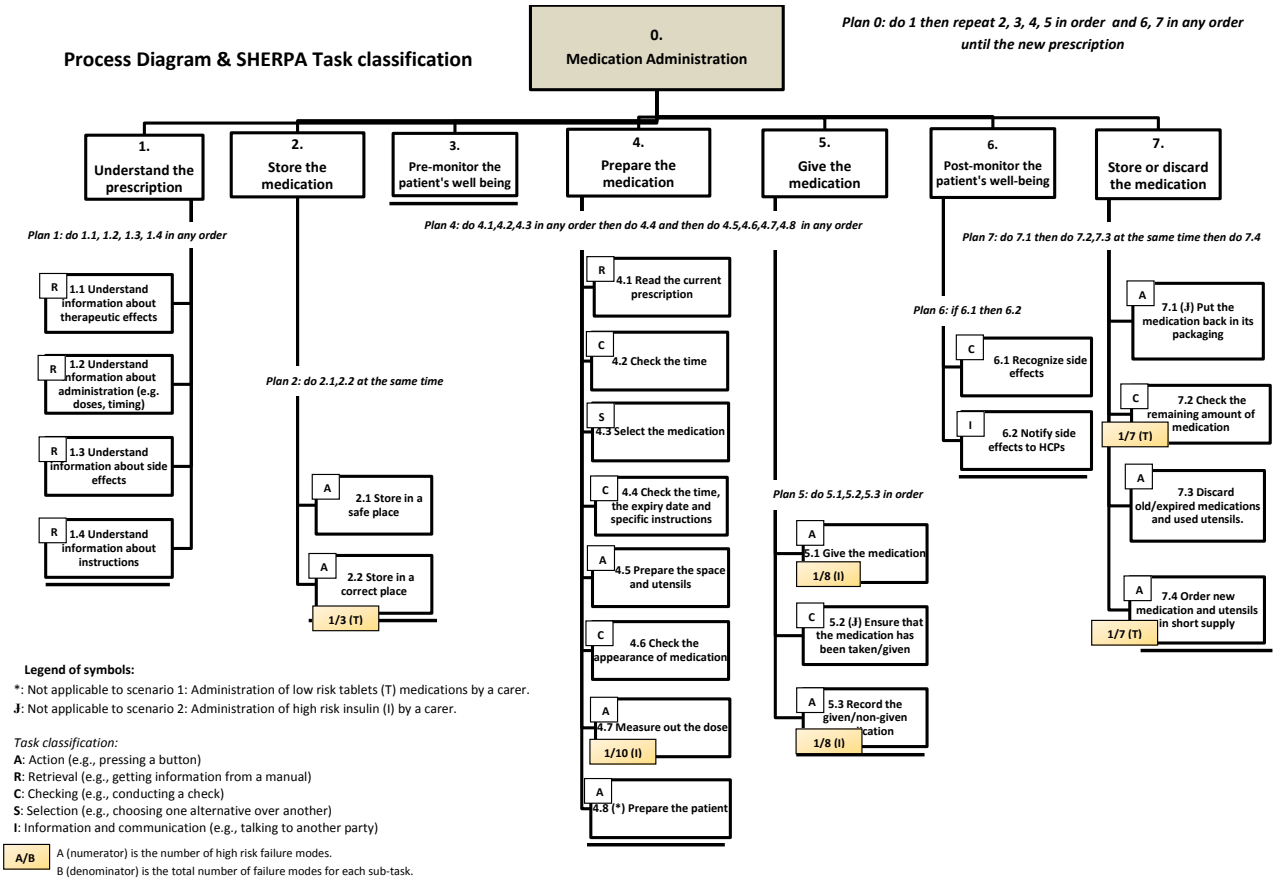


Figure 3 –HTA diagram of medication administration process and SHERPA task classification for high and low risk scenarios.

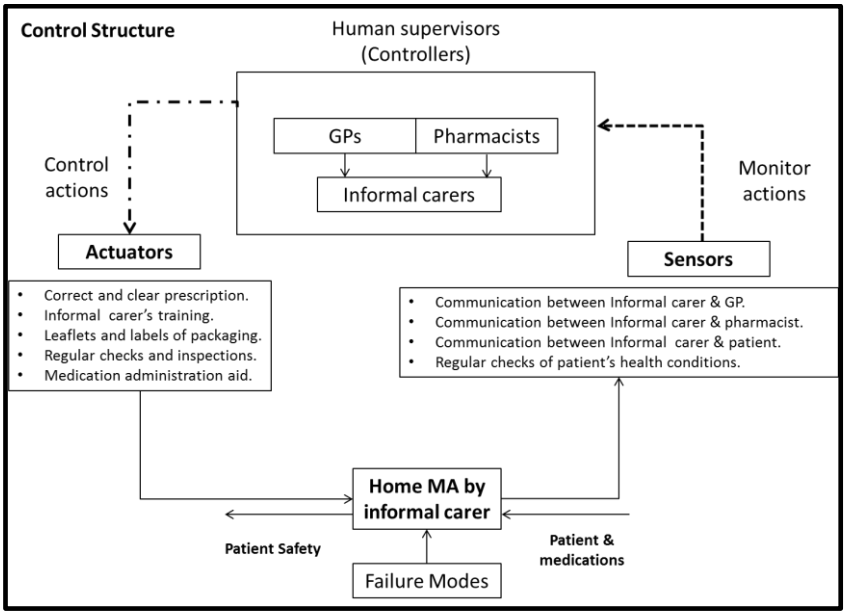


Figure 4 – STAMP-STPA: Operating Control Loop of medication administration by informal carers. [GPs = General Practitioners; MA = Medication Administration]

Hazard Analysis: identification, classification and filtering of failures

During the failure identification, the team recognised 34 failures that were classified into human errors using SHERPA's taxonomy with a good agreement (kappa=0.707) by two team members (AP & GF). This classification revealed that the most frequent human errors were: wrong action on the right object (7 of 34 failures), action omitted (7 of 34), check omitted (6 of 34), and incomplete information retrieval (4 of 34).

The failures were then scored by the team members with an individual scoring procedure, followed by a global discussion to reach consensus.

Once all the failures were scored, two researchers (AP & GF) applied SHERPA's step of consequence analysis to solve the discrepancies in the severity ratings. Once the hazard scores were recalculated, the failures were further analysed with the SHERPA's step of recovery analysis and the STAMP-STPA's step of identification of existing control measures. This action simplified the use of the decision tree and consequently the identification of the critical failures.

Cause Analysis

Once the critical failures were identified, their causes were analysed and classified according to a customised version of the STAMP-STPA taxonomy of causal factors. The generic scheme of STAMP-STPA taxonomy was adapted to fulfil the process of MA in home care. Particularly, the scheme was divided into three main parts: inadequate control measures (i.e., alarms, double checks, supporting materials, utensils, training), inadequate use of control measures (i.e., lack of checks, misuse of supporting materials, misuse of utensils, absence of training, ineffective training) and

inadequate exchange of information about the process (i.e., information provided by oversight, reports, measures of indicators - see Appendix B). The causal analysis showed that the failures were mainly caused by carers who do not adequately use possible control measures of the MA process, such as recording various types of information (e.g. the medications given, the date of order) or using organisational tools (e.g. spreadsheets, reminders).

Identification of prevention Measures and Controls

At the end of the causal analysis, during a brainstorming session, the team members identified feasible recommendations and solutions to prevent the critical failures. The majority of solutions were an improvement of the control measures already in place and for each recommendation the team identified the supervisor(s) and the outcome measures.. Later, the solutions were classified according to the SHERPA's step of Remedy Analysis in four classes: equipment (redesign or modification of existing equipment), training (inform/suggest the carer/patient on new procedures to follow), procedures (provision of new or redesign of old procedures) and organisational (changes in organisational policies or culture) . The majority of these solutions were classified as 'training', highlighting the importance of enhance the instructions on specific topics such as medication identification and storage, followed by 'the introduction of new or redesigned procedures'. For example, the failure 'The medication in short supply is not ordered' may be caused by the fact that the carers are too busy. To solve this, one of the proposed solution was the introduction of new procedures by using a plan to order medications. This solution was classified as a 'training' remedy because it means that the carers are trained to improve their organisational or IT skills (e.g. using spreadsheets, medication administration record charts) (Parand et al., in press). These results have been disseminated to community carer groups across the UK.

Finally, the recommendations, along with the supervisors and the outcome measures, were included into a new STAMP control loop (Figure 5). Specifically, the new STAMP control loop was enriched with an additional human controller (i.e. the community nurses that provide technical assistance to the informal carers); new sensors (i.e. Medication Administration Record - MAR), a useful tool that helps the controllers to assess the correctness of medicines taken at different times, and My Medication Passport - a customised pocket-sized booklet, designed to record details of patients medication with the functionality to keep track of their past and current medicines use (Barber et al., 2014).

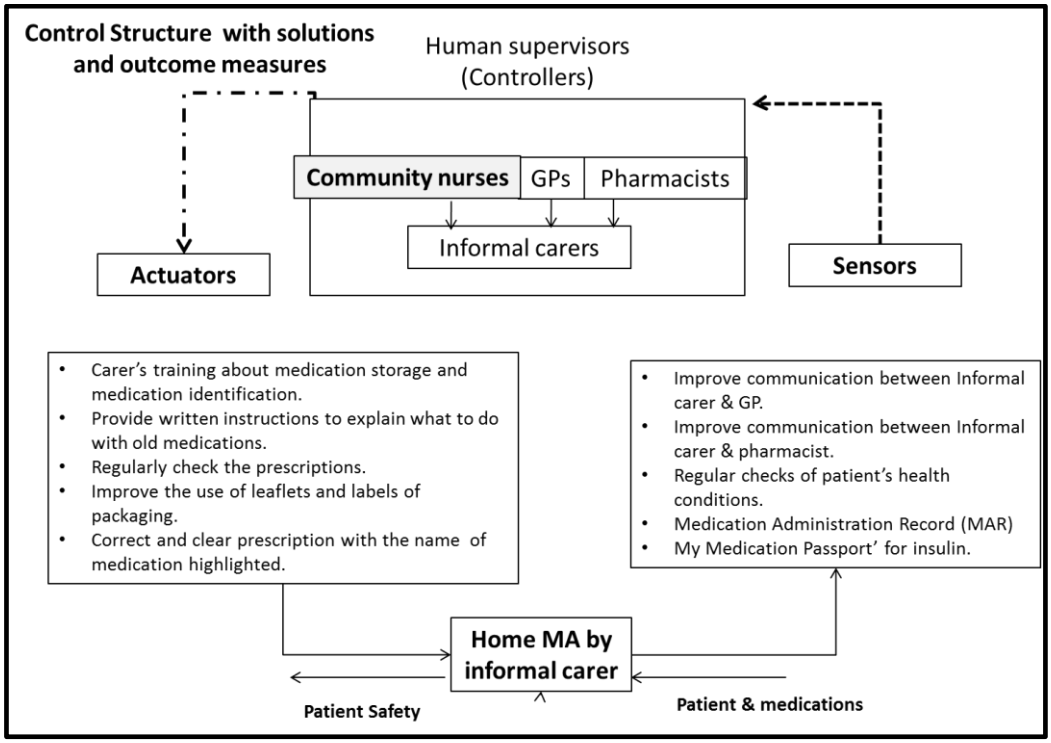


Figure 5 – STAMP: Control Structure upgraded with suggested solutions and outcome measures.[GPs = general practitioners; MA = Medication Administration]

Evaluation Survey

At the end of the analysis, an evaluation survey was conducted with the aim of identifying the advantages and disadvantages of the prospective analysis. The evaluation survey did not aim to demonstrate the superiority of the combined approach, although it represents a collection of team members' opinions and feedbacks about the methodology.

The most common advantages reported by the team were that it is a comprehensive, structured and systematic assessment tool to identify failures and their causes that allows different perspectives to shed light on processes. The primary disadvantages were that the procedure was hard work and is still subjective.

DISCUSSION

This study proposes an extended version of the traditional HFMEA.

HFMEA is a widely recommended method that has previously been applied to analyse numerous healthcare processes. HFMEA has several advantages, particularly, one of the most effective is the multidisciplinary nature of the team that leads the participants to gain an insight into daily practice and educate to the teamwork. The addition of The HFMEA criticisms (reported in Table 1) were addressed by implementing solutions proposed in literature and using SHERPA and STAMP-STPA to provide complementary findings.

Before starting the analysis, the topic of the analysis was described with scenarios and grounding rules (Shebl, Franklin, & Barber, 2009). The preparation in advance of documents (i.e., process diagram, list of failures) should reduce the duration of the analysis (Vlayen, 2011), (Shebl, Franklin, & Barber, 2012), (Habraken et al., 2009). In addition, the elaboration of documents prepared according to scientific findings aimed to reduce the subjectivity of the HFMEA methodology. The use of sub-teams resulted in a consensus of findings by means of a process of iterative review and refinement, which should have increased the validity of the results (Chadwick & Fallon, 2013).

Specifically, the hybrid method depicts the process with multiple diagrams, improving the clarity of the process for those involved (Franklin et al., 2012; Wetterneck et al., 2004). In particular, the box-and-arrow diagram describes the process as a flowchart and the SHERPA's HTA diagram offers a clear view of the specific tasks. The hazard analysis is enhanced with the classification of the failures into human errors (Franklin et al., 2012; Chadwick & Fallon, 2013). In addition, the hazard analysis was supported by the use of probability and severity scales with customised descriptors that helped the team members to assign ratings without personal interpretations, increasing the reliability of the results and preventing lengthy discussions about the exact meaning of probability and severity categories (Wetterneck et al., 2004; Vlayen, 2011; Shebl, Franklin, & Barber, 2012; Habraken et al., 2009; Chadwick & Fallon, 2013; Habraken et al., 2009). The procedure of scoring was based on individual ratings followed by a consensus procedure, shown to be one of the best scoring procedures (Ashley et al., 2010 a). The decision tree was also simplified.SHERPA helped to highlight the errors that may result from the incorrect order of the tasks and provided a taxonomy for the classification of failures into human errors. SHERPA's consequence analysis verified the consistency of severity scorings with the identification of HFMEA's discrepancies and contributed an explicit description of the effects/consequences of the failures, details that are not explicitly provided by the traditional HFMEA procedure. The taxonomies used by SHERPA provided an explicit guidance on which classification approaches could be used to enhance the description of HFMEA's results. The identification of the process' recovery points augmented the understanding of the process' activities and their single points of weaknesses.

STAMP-STPA provided an overview of the process' controls, improving the cause analysis (Antoine, 2013). In contrast to the traditional hazard analysis techniques, however, STAMP-STPA is more powerful in terms of identifying more causal factors and hazardous scenarios, particularly those related to software, system design, and human behavior. The safety control structure provides excellent documentation and a nice graphical depiction of the functional design of the system (Leveson et al. 2013). Finally, the team identified remedies starting from present solutions supporting the continuous improvement of the process (Chadwick & Fallon, 2013).

Table 4 summarises which tool (SHERPA and/or STAMP-STPA) addresses the HFMEA methodological criticisms previously described in Table 1 .

HFMEA criticisms	Solutions from literature	SHERPA	STAMP
Graphical description of the process			
The graphical representation of the process is too subjective	Prepare documents according to scientific findings.	/	/
The HFMEA box-and-arrow diagrams provide only minimum information	Improve the process representation using other diagram types	x	x
The HFMEA box-and-arrow diagrams does not include a description of the control measures	Use diagrams to describe the control measures		x
Hazard Analysis			
The definition of the potential failures is too subjective and there is a poor consultation of existing evidence	Prepare documents according to scientific findings.		
HFMEA does not require the description of the control measures of the analysed process	Perform a cause analysis with a system approach that takes into account the complexity of processes		x
HFMEA lacks analysis of human errors	Include human error taxonomy to identify human errors	x	
The rating procedure could be affected by personal interpretations of probability and severity scales	Adapt the rating scales to the analysed process and use an individual confirmatory procedure		
HFMEA does not require the identification of recovery points in the process	Extend the hazard analysis with the identification of recovery activities	x	
The decision tree results can be difficult to understand and use	Simplify and explain the decision tree		
Cause Analysis			
HFMEA does not consider the use of a system approach to analyse the causes and identify countermeasures	Perform a cause analysis with a system approach that takes into account the complexity of processes	x	x
Identification of recommendations			
HFMEA does not support the continuous improvement.	Define solutions as an improvement those already in use		

Table 4 - HFMEA criticisms addressed by solutions from literature, SHERPA and/or STAMP-STPA

Implications for theory and practice

The hybrid methodology shares the general structure of the proactive hazard analysis approaches: an experienced, multi-disciplinary analysis team is assembled, the process is mapped, the process is systematically examined by the team to identify potential risks and, lastly, documentation about the system is produced. This structure is built on a combination of three different methodologies and each combination brings methodological advantages. The integration of SHERPA and HFMEA offers a deep understanding of the process with a prominent human component; a FMEA and SHERPA combination was successfully applied to study the process of drug administration (Lane, Stanton, & Harrison, 2006). The combination with STAMP-STPA has the advantage to augment the causal analysis with more hazardous scenarios. STAMP-STPA control loop integrates the view of the process with a major focused on the control measures necessary to guarantee the safety of patients and the people that are in charge for it. FMEA and FMEA combination has given very good results in the domain of interoperability of medical devices (Procter et al., 2014).

Finally, the combination of SHERPA and STAMP brings together two methodologies traditionally thought of as rather separate, opening up a number of theoretical advances in ergonomics. SHERPA and STAMP-STPA may appear, at first glance, to be at opposite ends of the methodological spectrum; SHERPA is a classical, reductionist, task-based, error prediction approach, whereas STAMP-STPA is a non-reductionist, systems-based, approach. Nevertheless, at the core of both methods there is the error taxonomy (SHERPA has 24 error types and STAMP-STPA has 4 error types). On the face of it, SHERPA has a more sophisticated error taxonomy than STAMP-STPA. The main difference between the two methods is the form of representation that they use: SHERPA starts with a description of the tasks being performed whereas STAMP-STPA starts with the definition of the system hazards and a hierarchical model of the control system. SHERPA offers a bottom-up approach whereas STAMP-STPA is top-down. Experts in modern complex socio-technical systems design (such as healthcare organisations) have argued for both approaches to be used simultaneously to bring about improvements (Clegg, 2000; Walker at al., 2009).

LIMITATIONS AND FUTURE RESEARCH

A main limitation of this study is the impossibility to practically demonstrate, with multiple applications, that the proposed approach actually reduces the subjectivity and the time with an improvement of the reliability and the resource consumption. Future efforts will be focused on objectively assessing the amount of the additional benefits bought by SHERPA and STAMP-STPA as well as evaluating the reliability and the validity (Stanton, 2014). Although it is worth noting that the reliability and validity of SHERPA used independently has already been established (Baber and Stanton, 1996; Stanton and Stevenage, 1998, Stanton and Young, 1999, 2003).

CONCLUSION

Ensuring the safety of patients has become one of the most important challenges faced by healthcare professionals. The objective of the patient safety management is to prevent harm to patients, with the detection of the problems before they may occur. Currently most of the research and work in healthcare is undertaken using older tools, such as root cause analysis for accident investigation and HFMEA for hazard analysis. The use of these tools limits the usefulness of the analysis. Recent studies (Habraken et al., 2009) have demonstrated that the use of multiple methodologies is a convenient solution to increase the level of safety in complex practices because of the detailed level of information obtained with the complementary views of the process (Stanton et al, 2009). The present study argues that certain limitations of HFMEA can be overcome with the integration of two risk analysis methods already in use within healthcare and other settings. This combination extends HFMEA and maximise the benefits offered by risk analysis techniques not typically applied jointly – SHERPA and STAMP-STPA. HFMEA is a widely used method designed to analyse healthcare processes and the main structural steps of the hybrid approach were identified using HFMEA. Our study demonstrates that the combination of different methods could be worthwhile for the analysis of complex processes and is helpful to solve some of the critiques of HFMEA. The prospective application of the combined approach within the context of medication administration errors within domiciliary settings produced a rich set of accident causal factors with new solutions to prevent future accidents in medication administration process (Parand et al.,in press).

COMPETING INTERESTS

Sevdalis N. is the director of London Safety and Training Solution Ltd, which provides patient safety advisory and training services on a consultancy basis to hospitals in the UK and internationally. The other authors have no competing interests to declare.

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Appendix A - New worksheet of the combined approach.

Task & Subtask	SHERPA Error mode Classification	HFMEA Failure Mode	SHERPA Consequence and Critical Analysis	SHERPA Recovery points	HFMEA Hazard Analysis		
					Severity	Frequency	Hazard Score

Appendix B - Adapted STAMP taxonomy for the causes' classification

CONTROL

1. Inadequate control measures (alarms, checks and double checks, supporting materials, utensils, training):

    1.1 Missing control measures to identify/detect failures (e.g. missing alarm).
    1.2 Inappropriate, ineffective, control measures to prevent failures.
    1.3 Missing control measures to prevent failures.

USE OF CONTROLS

2. Inadequate use of control measure (lack of checks, misuse of supporting materials, misuse of utensils, absence of training, ineffective training):

    2.1 Inadequate reading/listening/understanding the information provided by control measures.
    2.2 Inadequate action of carer.
    2.3 Inadequate usage time (e.g. too late or too early).

EXCHANGE OF INFORMATION TO MONITOR THE PROCESS

3. Inadequate or missing information about the process provided by oversight, reports, measures of indicators:

    3.1 Missing systems to monitor the process.
    3.2 Inadequate arrival time of information.
    3.3 Inadequate action of carers or HCPs in giving information about the process (incorrect or no information provided).